

CLAIMS

Please amend the claims as the follows.

1. (Withdrawn) A ball prosthetic valve comprising
a T-shaped annular housing having an inner surface which defines a central passageway for the flow of a biological fluid therethrough; and
a sphere occluder entrapped in said T-shaped annular housing acting as a valve to open and close the passageway for the flow of the biological fluid unidirectionally from the main body to the two arms perpendicular to main body of the housing.
2. (Withdrawn) The ball prosthetic valve as in claim 1, wherein the T-shaped annular housing and the sphere occluder are formed of material selected from the group consisting of metal, ceramics, polymers, graphite and pyrolytic carbon.
3. (Withdrawn) The ball prosthetic valve as in claim 1, wherein the surface of the T-shaper annular housing and the surface of the sphere occluder are coated with pyrolytic carbon.
4. (Withdrawn) The ball valve as in claim 3, wherein the pyrolytic carbon is a composite comprising pyrolytic carbon, aligned nanometer sized pyrolytic carbon domains and carbon nanofibers.
5. (Withdrawn) The ball prosthetic valve as in claim 1, is implanted in a system comprising
a heart valve either an aortic, mitral, plumartumy, or tricupsular;
a valve in a transmyocardial revascularization device;
a valve in the veins;
a valve in the esophagus and at the stomach;
a valve in the cerebral fluid management;
a valve in the ureter and/or the vesica;

a valve in the lymphatic system;
a valve in the biliary passages; and
a valve in the intestines.

6. (Withdrawn) A method of fabricating a ball prosthetic valve, comprising the steps of: coating a graphite sphere with pyrolytic carbon to form a sphere occluder
polishing the surfaces of the sphere occluder
embedding the occluder into graphite or carbon to form a T-shaped mandrel
coating the surface of the T-shaped mandrel with pyrolytic carbon
removing the graphite or carbon core
polishing all the surfaces of and the T-shaped annular housing and the sphere occluder through abrasive flow

7. (Withdrawn) A monoleaflet prosthetic valve comprising:
an annular housing having an inner surface which defines a central passageway for biological fluid flow therethrough;
a single disc occluder mounted in the annular housing acting as a valve to allow and to stop the flow of biological fluid;
a pair of ears extending along opposite ends of an eccentric line across the occluder and interfiting with a groove of the annular housing, which guide the swings of the occluder between the open and close position; and
a frang-like outlet formed on an exterior surface of the annular housing which facilitates the attachment of the valve to the tissue.

8. (Withdrawn) The monoleaflet prosthetic valve as in claim 7, wherein the annular housing and the occluder are formed of material selected from the group consisting of metal, ceramics, polymers and pyrolytic carbon.

9. (Withdrawn) The monoleaflet prosthetic valve as in claim 8, wherein the pyrolytic carbon is a composite comprising pyrolytic carbon, aligned pyrolytic carbon nanometer sized domains and carbon nanofibers.

10. (Withdrawn) A method of fabricating a monoleaflet prosthetic valve, comprising the steps of:
coating a graphite disc substrate with pyrolytic carbon to form a disc occluder
machining and polishing the surfaces of the disc occluder
embedding the occluder into graphite or carbon to form a mandrel
coating the surface of the mandrel with pyrolytic carbon
removing the graphite or carbon core
polishing all the surfaces of and the annular housing and the occluder through abrasive flow

11. (Withdrawn) The monoleaflet prosthetic valve as in claim 7, is implanted in a system comprising
a heart valve either a aortic, mitral, plumartumy, or tricupsular;
a valve in a transmyocardial revascularization;
a valve in the veins;
a valve in the esophagus and at the stomach;
a valve in the cerebral fluid management;
a valve in the ureter and/or the vesica;
a valve in the lymphatic system;
a valve in the biliary passages; and
a valve in the intestines.

12. (Withdrawn) A monoleaflet prosthetic valve comprising:
an annular housing having an inner surface which defines a central passageway for biological fluid flow therethrough;

a single disc occluder mounted in the annular housing acting as a valve to allow and to stop the flow of biological fluid;

a pair of ears extending along opposite ends of an eccentric line across the occluder and interfiting with two hinges in the annular housing, which guide the occluder swings between open and closed positions;

a peripheral groove formed on an exterior surface of the annular housing which facilitates the attachment of the valve to the tissue; and

a frang-like outlet formed on an exterior surface of the annular housing which facilitates the attachment of the valve to the tissue.

13. (Withdrawn) The monoleaflet prosthetic valve as in claim 12, wherein the annular housing and the occluder are formed of material selected from the group consisting of metal, ceramics, polymers and pyrolytic carbon.

14. (Withdrawn) The monoleaflet prosthetic valve as in claim 12, wherein the annular housing and the occluder are sole pyrolytic carbon or coated with pyrolytic carbon.

15. (Withdrawn) The monoleaflet prosthetic valve as in claim 13, wherein the pyrolytic carbon is a composite comprising pyrolytic carbon, aligned nanometer sized pyrolytic carbon domains and carbon nanofibers.

16. (Withdrawn) The monoleaflet prothetic valve as in claim 12, is implanted in a system comprising

a heart valve either a arotic mitral plumartumy or tricupsular; a valve in a transmyocardial revascularization;

a valve in the veins;

a valve in the esophagus and at the stomach;

a valve in the cerebral fluid management;

a valve in the ureter and/or the vesica;

a valve in the lymphatic system;

a valve in the biliary passages; and
a valve in the intestines.

17. (Withdrawn) A bileaflet valve prosthesis comprising
an annular valve body having a central passageway extending therethrough;
and
a pair of valve leaflets and hinges supporting the pair of leaflets for
substantially pivotal movement on a pair of eccentric axes between a closed position
blocking the blood flow therethrough and an open position allowing blood flow therethrough,
wherein the leaflets each including guides projecting in opposite directions
along the pivotal axis,
said guides having a rounded bottom end,
said support hinges including pairs of generally triangular depression holes at
generally diametrically opposite locations,
each of said depressions having a curved top edge and generally straight outer
and inner edges which meet at a vertex,
said leaflet guides being received in said depressions with said bottom ends at
the vertex thereof,
said vertex being formed with a radius of curvature matched to the radius of
curvature of said bottom ends and providing pivot points for each bottom end,
whereby said leaflets each move between an open position wherein said
guides are located generally adjacent said outer edges and a closed position wherein said
guides are located generally adjacent said inner edges.

18. (Withdrawn) The bileaflet valve prosthesis as in claim 17, wherein the
valve body wall which forms said central passageway is the surface of a right circular
cylinder and wherein the major peripheral arcuate edge of each said leaflet is contoured so
that the surface of said major edge fits flush adjacent said passageway cylindrical wall.

19. (Withdrawn) The bileaflet valve prosthesis as in claim 17, wherein a minor peripheral edge of each leaflet is straight and the edge surface thereof is planar so that the planar surfaces of said minor edges abut each other in surface-to-surface contact when said valve leaflets are in the closed position.

20. (Withdrawn) The bileaflet valve prosthesis as in claim 17, wherein the plane of each of said leaflets in the closed position makes an angle of between about 60.degree. and about 80.degree. with the axis of said body, and where the plane of each of said leaflets in the open position makes an angle of between about 5.degree. and about 10.degree. with the axis of said passageway.

21. (Withdrawn) The bileaflet valve prosthesis as in claim 17, wherein the radius of curvature of said vertex is equal to or not more than 3% longer than the radius of curvature of said bottom end.

22. (Withdrawn) The bileaflet valve prosthesis as in claim 17, wherein each of said guides has an elongated vertical edge disposed generally perpendicular to said minor edge.

23. (Withdrawn) The bileaflet valve prosthesis as in claim 17, wherein the valve body wall which forms said central passageway is the surface of a right circular cylinder and wherein at least one protrusion from said valve body wall is provided to contact each leaflet and serve as close position stop means therefor.

24. (Withdrawn) The bileaflet valve prosthesis as in claim 17, wherein upstanding supports are provided in which said hinges are formed, said supports extending inward into said passageway and having surfaces formed thereon which stop said leaflets in the open and in the closed positions.

25. (Withdrawn) The bileaflet prosthetic valve as in claim 17, wherein the annular housing and the leaflets are formed of material selected from a group consisting of metal, carbon, ceramics, polymers and pyrolytic carbon.

26. (Withdrawn) The bileaflet prosthetic valve as in claim 11, wherein the annular housing and the occluder are sole or coated with pyrolytic carbon.

27. (Withdrawn) The bileaflet prosthetic valve as in claim 17, wherein wherein the pyrolytic carbon is a composite comprising pyrolytic carbon, aligned nanometer sized pyrolytic carbon domains and carbon nanofibers.

28. (Withdrawn) The bileaflet prothetic valve as in claim 17, is implanted in a system comprising

- a heart valve either a arotic, mitral, plumartumy, or tricupsular;
- a valve in a transmyocardial revascularization;
- a valve in the veins;
- a valve in the esophagus and at the stomach;
- a valve in the cerebral fluid management;
- a valve in the ureter and/or the vesica;
- a valve in the lymphatic system;
- a valve in the biliary passages; and
- a valve in the intestines.

29. (Currently amended) A tri-leaflet prosthetic valve comprising an annular valve body having an inner surface and being disposed around a central axis and three substantially identical leaflets mounted in said annular valve body and configured to translate between a closed position impeding blood flow through the valve and an open position allowing blood flow there through, said annular body having three pairs of symmetrically placed hinges extended from ~~the rim of~~ said annular body for pivotally supporting said leaflets, each of said hinges having a plane of symmetry containing said central axis and an opening extending into the valve body

and each of said leaflets having opposed ears ~~for engaging said hinges~~

and a flat edge adjacent each of said ears ~~for engaging a surface segment~~

, with said ears pivotally received in said hinge openings, wherein each of said openings include a hole extending entirely through the valve body.

30. (Currently amended) The tri-leaflet prosthetic valve as in claim 29, wherein each of said leaflets further **comprising** **comprise** a central surface having a curved outer edge for engaging the inner surface of said annular body and an obliquely angled inner edge for engaging adjacent leaflets.

31. (Original) The tri-leaflet prosthetic valve as in claim 29, wherein each hinge further comprises stop means for arresting movement of the leaflets.

32. (Previously presented) The tri-leaflet prosthetic valve as in claim 29 further comprising at least three supports for guiding said leaflets, each of said supports comprising two flat planes on said inner surface of said support.

33. (Currently amended) The tri-leaflet prosthetic heart valve according to claim 29 wherein each of said leaflets further **comprising** **comprise** a central surface having a curved outer edge for engaging the inner surface of said annular body and an obliquely angled inner edge for engaging adjacent leaflets; and two flat segments adjacent to each ear to guide the motion of **the** said leaflet.

34. (Currently amended) The tri-leaflet prosthetic valve as in claim 29 wherein the valve body and the leaflets are formed of ~~material~~ **materials** selected from the group consisting of metal, graphite, polymers, ceramics, carbon composite, pyrolytic carbon, and nanostructure engineered carbon.

35. (Previously presented) The tri-leaflet prosthetic valve as in claim 29, wherein the valve body and the leaflets are further coated with nanostructure engineered carbon.

36. (Currently amended) The tri-leaflet prosthetic valve as in claim 29, wherein the valve body and the leaflets ~~are formed of~~ include nanostructure engineered carbon.

37. (Currently amended) The tri-leaflet prosthetic valve as in claim ~~34~~ 29, wherein the valve body and the leaflets ~~are formed of carbon composite~~ include a composite layer including pyrolytic carbon and pyrolytic carbon nano fibers.

38. (Currently amended) The tri-leaflet prosthetic valve as in claim 29, wherein the internal opening shape of the hinges is selected from the group consisting of triangular, circular ~~or and~~ butterfly.

39. (Currently amended) The tri-leaflet prosthetic valve as in claim 29, wherein the hinge openings have a bottom surface ~~of the hinges~~ is shape selected from the group of shapes consisting of flat, spherical depression and spherical protrusion.

40. (Currently amended) The tri-leaflet prosthetic valve as in claim 29, wherein the ~~bottom of the hinges hinge opening holes is open or half open all the way though the wall are only about half the size of the openings take up only about half of the hinge opening bottom~~.

41. (Withdrawn) Method of fabricating prosthetic valves as in claim 12, 17 or 29, comprising the steps of:

coating a leaflet substrates with pyrolytic carbon

machining and polishing the surfaces of the leaflets embedding the leaflets into graphite or carbon to form a mandrel

coating the surface of the mandrel with pyrolytic carbon

removing the graphite or carbon core

polishing all the surfaces of and the annular housing and the leaflets through abrasive flow

42. (Withdrawn) A method of making a valve substrate comprising the steps of: providing a mixture of graphite or carbon powder from 10 to 80 wt %, commercial chopped carbon fibers or carbon nanofibers from 10 to 80 wt % and organic thermosetting binders between 5- to 10 wt %; doping the mixture with 5-10 wt % high density refractory radio opaque metals such as tungsten, W and Tantalum, Ta; molding the valve substrates green body; carbonizing the green body in inert gas at temperature higher than 1800.degree. C.

43. (Withdrawn) A method of coating a substrate with a nanostructurally engineered pyrolytic carbon comprising the steps of:

Providing a reactor system with heating element, reactor chamber, insulation, chemical introducing and exhaust treatment systems, and particle feeding and withdrawing systems, wherein the reactor chamber contains single or multiple gas introducing ports;

Loading a pre-machined substrate in the reactor chamber filled with a media;

Introducing chemicals comprising hydrocarbons and mixtures of propane and methane, and catalysts of organic metallic compounds comprising transition metals, alloy and oxide particles;

Incorporating vapor grown carbon fibers into the high density pyrolytic carbon matrix to have randomly spaced junctions between individual fibers during in situ growth of said vapor grown carbon fibers; and

Removing the substrate from the reactor chamber.

44. (Withdrawn) The method as in claim 43, wherein the vapor grown carbon fibers are formed by flowing a gas mixture of hydrocarbons and mixtures of hydrogen and nitrogen into the reactor chamber which has been seeded with transition metal catalyst particles, wherein the catalyst can be converted from organic-metallic compounds or fine size transition metal or alloy or oxide.

45. (Withdrawn) The method as in claim 43, wherein the vapor grown carbon fibers are grown and incorporated with pyrolytic carbon by heat treatment at a temperature between 300 and 2800.degree. C.

46. (New) The tri-leaflet prosthetic valve as in claim 29, in which the valve body includes an outer coating comprising nanostructurely aligned carbon.

47. (Withdrawn) The method as in claim 43, wherein the hydrocarbon comprising at least 10% by volume of said chemicals.

48. (Withdrawn) The method as in claim 43, wherein the chemicals and catalysts are introduced from the bottom ports of the reactor chamber.

49. (Withdrawn) The method as in claim 43, wherein the vapor grown carbon fibers are incorporated into pyrolytic carbon coating matrix producing a nanostructurally engineered pyrolytic carbon. In the preferred embodiment of the coating material, the properties of the coating at the interface with the substrate is closely matched with those of the substrate so there is a minimum residual stress and good bonding. The center layer of the coating is incorporated with carbon nanofiber to gain mechanical strength and retard the crack formation and propagation. The surface layer of the valve prosthesis, however, is nanostructurely engineered in a way that all the graphitic domains are preferred aligned so that the surface is formed of the graphitic basal planes through the control of the coating parameters. The surface of the final device consists of parallel-aligned graphite basal plane domains.

50. (Currently amended) The tri-leaflet prosthetic valve as in claim ~~37~~ 29, wherein the leaflets include a carbon composite ~~is-formed of material selected from~~ the group consisting of graphite, carbon powder, chopped carbon fibers, carbon ~~nonofibers~~ nanofibers and organic thermosetting binders, and combinations thereof.

51. (Currently amended) The tri-leaflet prosthetic valve as in claim 36, wherein the nanostructure engineered carbon ~~is-an-~~ includes a surface having

aligned nanometer sized graphite-carbon domains ~~or a composite of nanostructure engineered carbon is an aligned nanometer and carbon nanofibers.~~

52. (New) A tri-leaflet prosthetic valve comprising:

an annular valve body having an inner surface, a passageway therethrough, and disposed around a central axis;

three leaflets pivotally coupled to said annular valve body and configured to translate between a closed position impeding blood flow through the valve body passageway and an open position allowing blood flow through the passageway, said annular body having three pairs of hinges for pivotally coupling to said leaflets, each of said hinges having an inner surface, an outer surface, a thickness, and an opening extending into the hinge inner surface; and

each of said leaflets having a pair of ears, with each of said ears pivotally received in one of said hinge openings, wherein at least part of said opening extends through the hinge thickness to provide fluid passage through said hinge opening.

53. (New) The valve of claim 52, in which the hinge openings have a shape selected from the group consisting of triangular, circular, symmetric butterfly, and asymmetric butterfly.

54. (New) The valve of claim 52, in which the opening has a bottom having an area, and in which the opening part extending through the hinge thickness occupies about half of the bottom area.

55. (New) The valve of claim 52, in which the opening and the opening part extending through the hinge thickness have substantially the same area.

56. (New) The valve of claim 52, in which the hinges protrude into the central passageway.

57. (New) The valve of claim 52, in which the valve body includes a composite including pyrolytic carbon and carbon nanofibers.
58. (New) The valve of claim 57, in which the valve body includes an outer coating comprising nanostructurely aligned carbon.
59. (New) The valve body of claim 57, in which the valve body includes a surface consisting of parallel aligned graphitic basal plane domains.
60. (New) The valve of claim 52, in which the leaflets include a composite including pyrolytic carbon and carbon nanofibers.
61. (New) The valve of claim 60, in which the leaflets include an outer coating comprising nanostructurely aligned carbon.
62. (New) The valve body of claim 60, in which the leaflets include a surface consisting of parallel aligned graphitic basal plane domains.
63. (New) The valve body of claim 52, further comprising an upstream rim having sewing holes therethrough.
64. (New) A tri-leaflet prosthetic valve comprising:
- an annular valve body disposed around a central axis, the valve body having a passageway therethrough; and
- three leaflets pivotally coupled to said annular valve body and configured to translate between a closed position impeding blood flow through the valve body passageway and an open position allowing blood flow through the passageway;
- in which the valve body includes a composite including pyrolytic carbon and carbon nanofibers.
65. (New) The valve of claim 64, in which the valve body includes an outer coating comprising nanostructurely aligned carbon.

66. (New) The valve body of claim 64, in which the valve body includes a surface consisting of parallel aligned graphitic basal plane domains.
67. (New) The valve body of claim 65, in which the valve body includes a surface having parallel aligned graphitic basal plane domains.
68. (New) The valve body of claim 64, in which the valve body includes a substrate, in which the composite is disposed over of the substrate.
69. (New) The valve of claim 68, in which the composite includes an engineered layer having properties which are close to substrate properties near the substrate and which properties change further from the substrate.
70. (New) The valve of claim 68, in which the substrate includes carbon fiber reinforced graphite.
71. (New) The valve of claim 68, in which the substrate includes a carbon nanofiber reinforced graphite.
72. (New) The valve of claim 68, in which the substrate includes a high density radiopaque material.
73. (New) The valve of claim 68, in which the substrate includes
between about 10 and 80 percent graphite or carbon powder;
between about 5 and 20 percent organic binders; and
between about 5 and 10 percent high density radiopaque material.
74. (New) A tri-leaflet prosthetic valve comprising:
an annular valve body disposed around a central axis, the valve body having a passageway therethrough; and

three leaflets pivotally coupled to said annular valve body and configured to translate between a closed position impeding blood flow through the valve body passageway and an open position allowing blood flow through the passageway;

in which the leaflets include a composite including pyrolytic carbon and carbon nanofibers.

75. (New) The valve of claim 74, in which the leaflets include an outer coating comprising nanostructurely aligned carbon.

76. (New) The valve body of claim 74, in which the leaflets include an outer surface consisting of parallel aligned graphitic basal plane domains.

77. (New) The valve body of claim 74, in which the leaflets include an outer surface having parallel aligned graphitic basal plane domains.

78. (New) The valve body of claim 74, in which the leaflets include a substrate, in which the composite is disposed outside of the substrate.

79. (New) The valve of claim 78, in which the composite includes an engineered layer having properties which are close to substrate properties near the substrate and which properties change further from the substrate.

80. (New) The valve of claim 78, in which the substrate includes carbon fiber reinforced graphite.

81. (New) The valve of claim 78, in which the substrate includes carbon nanofiber reinforced graphite.

82. (New) The valve of claim 78, in which the substrate includes high density radiopaque material.

83. (New) The valve of claim 78, in which the substrate includes

between about 10 and 80 percent graphite or carbon powder;

between about 5 and 20 percent organic binders; and

between about 5 and 10 percent high density radiopaque material.

84. (New) A tri-leaflet prosthetic valve comprising:

an annular valve body disposed around a central axis, the valve body having an interior passageway therethrough and an exterior region outside of the valve body; and

three leaflets pivotally coupled to said annular valve body and configured to translate between a closed position impeding blood flow through the valve body passageway and an open position allowing blood flow through the passageway;

in which the leaflet pivotal coupling includes leaflet pivotal coupling in an opening extending into the valve body, with at least part of the opening extending through the valve body such that fluid can flow from the passageway through the opening to the valve exterior region.

85. (New) The valve of claim 84, in which the valve includes hinges for providing the leaflet pivotal coupling, in which the hinges protrude into the passageway.

86. (New) The valve of claim 84, in which the valve includes hinges for providing the leaflet pivotal coupling, in which the hinges have a thickness having the openings extending into the thickness, in which at least part of the openings extend through the hinge thickness to provide the fluid flow through the hinge opening.

87. (New) A tri-leaflet prosthetic valve comprising:

an annular valve body disposed around a central axis, the valve body having a passageway therethrough; and

three leaflets pivotally coupled to said annular valve body and configured to translate between a closed position impeding blood flow through the valve body passageway and an open position allowing blood flow through the passageway;

in which the leaflets include an outer surface having parallel aligned graphitic basal plane domains.

88. (New) A tri-leaflet prosthetic valve comprising:

an annular valve body disposed around a central axis, the valve body having a passageway therethrough; and

three leaflets pivotally coupled to said annular valve body and configured to translate between a closed position impeding blood flow through the valve body passageway and an open position allowing blood flow through the passageway;

in which the valve body includes an outer surface having parallel aligned graphitic basal plane domains.